

REMARKS/ARGUMENTS

The Office Action has rejected all claims under a combination of 35 U.S.C. §102 and 103. In light of the amendments above and the arguments below, Applicants respectfully request reconsideration.

On October 29, 2007, inventor Janis Eells and Attorney Jean C. Baker interviewed Examiner Johnson. Applicants and their attorney thank the Examiner for the courtesy of his time and for his helpful suggestions.

Applicants reviewed the §102 and §103 rejections with the Examiner. Applicants also transmitted a draft copy of this response to Examiner Johnson. Applicants have summarized their §102 and §103 arguments below as they were presented to the Examiner. While continuing to dispute Examiner's characterization of the references in relation to the §102 rejection, Applicants have now amended claim 1 with the limitation found in claim 9, which was not rejected under §102. Applicants believe that the §102 rejections are now moot but present their argument in the interest of a complete record.

Applicants note that the original limitation with claim 9 was to "wherein the treatments are administered 2-3 times per day." Applicants have amended claim 1 (with similar language in claims 15 and 16) to "wherein the treatments are administered at least 2-3 times per day."

Applicants note that page 12 of the specification describes "success in treatment of acute ocular injuries with as few as two, preferably three or more, treatments..."

REJECTION UNDER 35 USC §102

Claims 1-7 and 10-14 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,599,891 to North et al. The Examiner alleges that North teaches a method for treating macular edema using light with a wavelength of between 550 and 695 nanometers with a preferred dosage between 1 and 50 J/cm². Applicants disagree that North et al. anticipates the present invention.

Specifically, claim 1, from which claims 2-7 and 10-14 depend, recites exposing the patient to light having a wavelength between 630 – 1000 nm and intensity between 10 – 90 mW/cm² for 1 – 3 minutes, and observing restoration or protection of visual function. In contrast, North teaches administering an effective amount of a photosensitizer to the patient and irradiating the patient with light having a wavelength absorbed by the photosensitizer. Thus,

Applicants respectfully submit that North does not teach every element of the present claims. In fact, North teaches away from the present claims, by teaching PhotoDynamic Therapy (PDT) to treat macular edema. Critical to the success of PDT, and to the teachings of North, is the use of the photosensitizer, a chemical compound that can be excited by light of a specific wavelength. North teaches the use of PDT to kill injured cells using a photactivatable chemical administered to the patient in combination with light. In contrast, the present invention works by healing injured cells using only far-red to near-infrared light by activating endogenous cytochrome c oxidase in cellular mitochondria to generate energy.

Applicants have now amended independent claims 1, 15 and 16 to emphasize elements of Applicants' invention that are absent from the North et al. document. Claim 1 is drawn to treatment "wherein the number of metabolically active neurons has increased" (see Fig. 8). Claim 15 specifies that the exposure "is in the absence of a photosensitizer" (see Example section, where there is no mention of addition of a photosensitizer). Claim 16 emphasizes that the light treatment is such that "rod and M-cone ERG amplitude has increased relative to tissue that hasn't been exposed to the light treatment" (see Fig. 2). Each of these claim elements emphasizes the difference between Applicants' invention and the method of North et al, which is destruction of cellular tissue.

Therefore, Applicants respectfully submit that North does not anticipate every element of claims 1-7, 10-14, and new claims 15-16 and these claims are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

As mentioned above, Applicants presented the argument above in their telephonic interview with Examiner Johnson. While not agreeing with the Examiner's characterization of the references, Applicants have elected to amend claim 1 and new claims 15 and 16 with the limitations of claim 9, which was not rejected under 35 USC §102. Applicants believe the §102 references are now moot.

REJECTION UNDER 35 USC 103

Claims 8-9 are rejected under as being unpatentable over North and further in view of Rosner et al. "Dose and Temporal Parameters in Delaying Injured Optic Nerve Degeneration by Low-energy Laser Irradiation," *Laser Surgery Med.* 13:61 1-617, 1993 (Rosner).

North is discussed above. North describes administering to a patient an effective amount of a photosensitizer compound and irradiating said compound with light to kill injured cells. The

Examiner alleges it would have been obvious to use the methods of North to treat eye injury or damage according to the present claims. However, nothing in North teaches or suggests that removing the photosensitizer compound would be feasible, let alone successful. In fact, North teaches away from such a modification, as the key to PDT is the use of the photosensitizer compound. Applicants respectfully submit that one of skill in the art would not be motivated to modify the teachings of North to achieve the present claims. Given the attached description of PDT, this is especially true. Because North et al. focused on killing injured cells using a photoactivatable chemical, one who understood the purpose of the North et al. technology would not combine that technology with treatments that "are administered at least 2 - 3 times per day."

Regarding Rosner, the Examiner alleges that Rosner teaches the use of low energy laser radiation once a day for 14 days to delay the degeneration of injured optic nerves. However, with North removed as a reference, Applicants do not believe that the Examiner's cited combination teaches the present invention. However, Applicants also point out that even if North were prior art, Rosner does not combine to teach the present invention because Rosner states explicitly that "non-coherent infrared light was ineffective or adversely affected the injured nerves..." [from the Abstract]. The authors conclude:

1. Coherent 632.8 nm He-Ne laser stimulation at an energy density of 40-132 J/cm² delays post-traumatic degeneration of the injured optic nerve.
2. Non-coherent 904 + 20 nm LED stimulation at an energy density 17-25 J/cm² was ineffective or adversely affected the injured nerves.

Applicants claim and describe protection at wavelengths between [claim 1] 630 –1000 nm and [claim 3] 670 – 900 nm. Applicants also claim and describe optimal energy densities of [claim 5] 2 – 10 J/cm² or [claim 4] 0.5 – 20 J/cm². Rosner teaches that Applicants' method of NIR-LED would not work because the light is (1) non-coherent and (2) the energy density is too low. According to these authors, one must use coherent laser light and the energy density would need to be at least 40 J/cm².

In short, Rosner strengthens Applicants' argument that their claims are not obvious because Rosner directly states that NIR LED treatment at an energy density between 17-25 J/cm² is ineffective or harmful. Additionally, the Examiner cites Rosner as teaching the use of low energy radiation "once a day for 14 days" not "at least 2-3 times a day", as all the independent claims now require.

SUMMARY

The application is believed to be in condition for allowance and allowance of the same is requested.

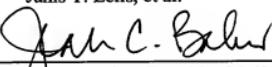
No extension of time is believed due, but should any additional extension be due, in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the extension fee to Deposit Account No. 17-0055. No additional fees are believed due; however, if any fees are due, in this or any subsequent response, please charge Deposit Account 17-0055.

Respectfully submitted,

Janis T. Eells, et al.

Date: November 29, 2007

By:


Jean C. Baker, Reg. No. 35,433
Quarles & Brady LLP
Attorney for Applicant
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497
414/277-5709